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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,417	07/08/2003	David Stinson	29914-703.201	7968

21971 7590 08/19/2005

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EXAMINER

ARAJ, MICHAEL J

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/615,417

Applicant(s)

STINSON ET AL.

Examiner

Michael J. Araj

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34-38 is/are allowed.
- 6) ☒ Claim(s) 1-12, 24, 27, 39-43, 46, 57-59, 61, 62, 65 and 66 is/are rejected.
- 7) ☒ Claim(s) 13-23, 25, 26, 28-33, 44, 45, 47-56, 60, 63, 64 and 67-77 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date see other.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: IDS dates.

IDS dates:

11/19/03

11/03/04

06/20/05

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

The reference, "bearing element" has been used with 38, 52, 80 and 130 throughout the specification.

The reference, "bearing surface" has been used with 40, 54, 82 and 132 throughout the specification.

Additionally, on page 12, line 11 and line 12 in the detailed description of the specification is objected to because reference character "bearing element" has been used to designate both 54 and 52, respectively.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 12 is rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 12, line 2, applicant positively recites part of a human, i.e. "attachment mechanism traverses a midline of the vertebra". Thus claim 12 includes a human within its scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive

property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12,24,27,39-43,46,57-59,61,62,65 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Senegas (WO 01/28442 A1). Senegas discloses a prosthesis with an artificial facet joint bearing element (2) adapted and configured to replace the cephalad portion of the natural facet joint and a fixation mechanism (4a) configured to be attachable to the artificial facet joint bearing element (2) to the vertebra without penetrating any bone portion of the vertebra or blocking access to a pedicle portion of the vertebra. The fixation mechanism (4a) is adjustable and adapted to attach to the spinous process location where at least two opposing sides and four surfaces of the lamina portion of the vertebra are contactable. (This identified because the fixation mechanism wraps around the superior and inferior spinous processes.) Also disclosed is an attachment mechanism (14a) that can attach the artificial facet joint bearing element (2) to the fixation mechanism (4a). With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Senegas which is capable of

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being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Allowable Subject Matter

Claims 34-38 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: Claims 34-38 in the instant application have not been rejected using prior art because no references, or reasonable combination thereof, could be found which disclose, or suggest, a prosthesis to replace right and left cephalad portions of right and left natural facet joints on a vertebrae having right and left facet joint bearing elements and a fixation mechanism adapted to attach the facet joint bearing element to a lamina portion of the vertebra without penetrating any bone portion of the vertebra. It is noted that in all of the art found, one could find a prosthesis to replace a cephalad portion of a natural facet joint on a vertebra. However, the prosthesis does not have a portion penetrating the vertebral bone as well as a portion that does not penetrate the bone for fixation purposes.

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Claims 13-23,25,26,28-33,44,45,47-56,60,63,64 and 67-77 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Araj whose telephone number is 571-272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MJA


EDUARDO C. ROBERT
PRIMARY EXAMINER